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EXAMINER

PALENIK, JEFFREY T

ART UNIT

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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,715	Applicant(s) WANNERBERGER ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 Feb. and 13 Feb. 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendments and remarks filed 13 February 2009 are acknowledged and entered on the record. The Examiner acknowledges the following:

Claims 2 and 8-12 have been cancelled.

Claims 1, 3-7, 13 and 14 have been amended. Claim 1 incorporates the limitation "an agent that provides a pH in the range of 3.0 to 6.2 as measured" from cancelled claim 2. The limitation "when 1 g of said tablet is slurried in 2 mL of water at 25°C" is a new limitation not previously presented or considered. Claim 1 has also been amended to include the limitations of cancelled claim 8 which have been further narrowed to a "compressed tablet". Said amendment further narrows the scope of the previous recitation of "solid dosage form" and thus narrows the scope of the overall invention.

Claims 3 and 4 have been amended to include the phrase "agent provides a..." for clarity with respect to amended claim 1.

Claims 4 and 5 have both been amended to remove the narrower (i.e. "preferably") limitations from the claims. The narrower limitation of claim 4 is presented in new claim 15, whereas the narrower limitation is recited in new claim 16. Thus the addition of new claims 15 and 16 are supported by Applicants' original recitation.

Claim 13 was previously an independent claim directed to a blister pack containing a pharmaceutical composition as defined by claim 9. Claim 13 has been amended to depend from claim 7 and the limitation "does not comprise fish gelatin" has been incorporated from cancelled claim 9. Thus the amendment is supported.

No new matter has been added.

Art Unit: 1615

Thus, claims 1, 3-7 and 13-16 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

Two new Information Disclosure Statements (IDS), filed on 3 February and 13 February 2009, are acknowledged and have been reviewed.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicant's amendment to the Abstract of the Invention has been considered fully and is persuasive. Thus, said objection has been **withdrawn**.

Rejection under 35 USC 112

Applicants' amendment to claims 1 and 5, as discussed above, render moot the rejections to claims 1, 3-7, 13 and 14, under 35 USC 112, second paragraph. Thus, said rejections have been **withdrawn**.

Rejection under 35 USC 102(b)

Applicants' amendment to claim 1, as discussed above, renders moot the rejection to claims 1 and 6, under 35 USC 102(b), as being anticipated by Applicants' own admission on the record regarding the trademarked product Minirin[®]. Thus, said rejection now stands **withdrawn**.

Art Unit: 1615

Applicants' amendment to the claims, particularly to claim 1, as discussed above, renders moot the rejection to claims 1, 3-5, 7 and 13, under 35 USC 102(b), as being anticipated by Flockhart et al. (USPN 5,298,256). Since Flockhart does not teach the dosage in the form of a compressed tablet, the claims are no longer anticipated. Thus, said rejection now stands **withdrawn**.

Rejection under 35 USC 103(a)

Applicants' remarks, which successfully exclude Nilsson et al. (WO 03/094886) as prior art under 35 USC §103(c), in combination with the amendments and remarks regarding Flockhart et al., are sufficient to render moot the rejection to claims 1, 3-7, 13 and 14 under 35 USC 103(a). Thus, said rejection now stands **withdrawn**.

NEW OBJECTIONS/REJECTIONS

In light of Applicants' amendments, as discussed above, as well as the newly added claims 15 and 16, the following rejections have been newly added:

CLAIM OBJECTIONS

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Presently amended, claim 3 depends from cancelled claim 2. The Examiner considers this to be a simple typographical error. Thus, since the limitations of

Art Unit: 1615

cancelled claim 2 have been incorporated into claim 1, the Examiner interprets claim 3 as depending from amended claim 1.

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 1 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited range of “acids” which function as pH controlling “agents” (see disclosure, pg. 4, lines 11-21), does not reasonably provide enablement for the incorporation of broader limitations of “agent” within claim 1 or “acid”, as further limited in the instant claim 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The recitations of “an agent” and “an acid” represent extremely broad limitations which suggest that the claims encompass a range of potential compounds, the scope of which is neither discussed nor supported by the instant disclosure. Given their broadest reasonable interpretations, the recitations of “an agent” and/or “an acid”, is deemed by the Examiner as directed towards any agent or acid which is capable of eliciting the desired effect, namely, providing a pH in the range of from 3.0 to 6.2 as measured when 1 g of the instantly claimed tablet is slurried in 2 mL of water at 25°C. To this end, given that the instant invention provides support for the incorporation of only limited number of acids which can accomplish said effect(s), the Examiner respectfully submits that one of ordinary

Art Unit: 1615

skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is seemingly concerned with an extremely limited subclass of agents and acids, and the ordinary practitioner would need to undergo undue experimentation in order to develop the instantly claimed composition without seeking further guidance from the prior art. As such, the disclosure of the instant specification is not sufficient to support the generically claimed limitations of “an agent” or “an acid”.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1615

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fein (US Pre-Grant Publication N° 2004/0138098).

The instantly amended claim 1 is directed to a blister pack which comprises a compressed tablet. Said tablet comprises desmopressin, an agent which provides a pH in the range of 3.0-6.2 when dissolved, and a pharmaceutically acceptable adjuvant, diluent or carrier. With regard to the agent limitation recited in claim 1, which states that it “provides a pH in the range of from 3.0 to 6.2 as measured when 1 g of said tablet is slurried in 2 mL of water at 25°C”; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the compressed desmopressin/agent composition, which is instantly claimed. Amended claims 3, 4 and 15 further limit the pH range recited in claim 1 which results from the inclusion of the agent. Amended claim 5 and new claim 16, respectively, further limit the agent to an acid, such as hydrochloric, malic or citric acid. Claims 6 and 14 recite limitations to the material of the blister pack. Claim 7 recites that the tablet of claim 1 does not comprise an enteric coating. Claim 13 recites that the tablet of claim 7 does not comprise fish gelatin.

Fein teaches an article of manufacture comprising packaging material and a pharmaceutical composition contained within said packaging material which comprises desmopressin (claim 14). Said pharmaceutical composition is taught as being adapted for

Art Unit: 1615

different delivery routes such as transmucosal (claim 5) and is further and preferably taught as being formulated into a hard, compressed, rapidly dissolving tablet which is adapted for oral dosing ¶[0040]. Paragraphs [0050] through [0052] teach that when formulated as a rapidly dissolving tablet, an additional component called an “effervescent couple” is used which is defined as a compound which emits gas on exposure to water or saliva ¶[0052]. The effervescent couple is taught as being the reaction product of a soluble acid source and a carbonate source. Such acids which may be used include malic and citric acids. Paragraph [0091] further teaches the inclusion of pH adjusting agents to adjust the pH of a solution from which the dosage form is prepared. Ranges which are targeted are from 3-6, preferably from 3.5 to 5.5 and most preferably from pH 4 to 5 (e.g. 4.5 or 4.8). Citric, hydrochloric and malic acids are expressly taught as the acids with which this adjustment is best accomplished with citric acid being preferred. Paragraph [0086] teaches that the shaped pharmaceutical dosage forms may include ingredients beyond the active agent such as adjuvants or a carrier (see also claim 1). Paragraph [0040], which specifically discusses tablet formulations teaches adjuvants such as a non-direct compression filler, wicking agent and a lubricant. Thus the limitations of claims 1, 3-5, 15 and 16 are expressly taught. Example 1 expressly teaches that blister laminate packaging may comprise PVC coated with PVdC ¶[0119], thereby teaching the limitations of claims 6 and 14. The teachings of Fein are silent to tablets which have any form of coating, not just enteric coatings, thereby teaching the limitation of claim 7. Lastly, Fein teaches several carrier compounds which may be used as alternatives for fish-gelatin and gelatin in general ¶[0085], thereby expressly suggesting that the tablet need not comprise fish-gelatin, as instantly claimed.

Art Unit: 1615

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have produced a solid dosage formulated as a compressed tablet under the guidance of Fein, contained it within a PVC/PVdC based blister package, also as suggested by Fein, and arrive at the instantly claimed composition. The ordinarily skilled artisan would have been highly motivated to formulate the instantly claimed tablet particularly since Fein expressly discusses the combining desmopressin with citric, hydrochloric or malic acids, for the express purposes of maintaining the pH of the dosage form within the ranges which are instantly claimed. Further motivation would have been derived based on the fact that Fein is not only silent to the use of tablet coatings, but also since numerous alternative carriers to fish gelatin are expressly taught. Containment of tablets and other dosage forms within PVC- and/or PVdC-based blister packaging is well known in the art for the purposes as common as protection and longevity of storage, as evidenced for example, by Remington (pp. 1492-1493).

Based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

Art Unit: 1615

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615